

In the Claims

Please cancel claim 7 without prejudice. Applicants reserve the right to pursue the original subject matter in a continuing application. Please amend claims 1, 8, 10, 11, 28; and add claim 33 as follows.

1. (Currently Amended) A method for assessing and evaluating a cleaning process comprising:

providing biofilm matrices on a support;

subjecting the support and biofilm matrices to the cleaning process to be assessed and evaluated; and

evaluating the cleaning process by analyzing the support for the presence of remaining biofilm matrices, including:

contacting the support with a biofilm-specific indicator and detecting any indicator present on the support.

2. (Original) The method of claim 1, wherein the cleaning process includes a decontamination process selected from the group consisting of washing, disinfecting, sterilizing, and combinations thereof.

3. (Original) The method of claim 1, wherein the support is a portion of an interior of a simulated endoscope.

4. (Original) The method of claim 1, wherein the support is positioned inside a simulated endoscope.

5. (Previously Presented) The method of claim 1, wherein the support comprises a chamber containing the biofilm matrices, wherein the chamber is attached to and in fluid communication with a simulated endoscope.

6. (Previously Presented) The method of claim 5, wherein the chamber has known light transmitting or light absorbing properties, and the step of analyzing the support for the presence of remaining biofilm matrices comprises passing a light beam through the chamber and detecting the transmitted or absorbed light; wherein a change from the known properties in the transmitted or absorbed light is indicative of the presence of biofilm matrices.

7. (Cancelled)

8. (Currently Amended) The method of claim 1 7, wherein the biofilm-specific indicator is a biofilm-specific dye and the detecting step comprises directing a dye-specific light source at the support and receiving light emitted or transmitted by the dye in a light detector.

9. (Cancelled)

10. (Currently Amended) The method of claim 1 7, wherein the indicator specifically binds a polysaccharide component of the biofilm matrices.

11. (Currently Amended) A method for assessing and evaluating a cleaning process comprising:

(a) contaminating a support with a known biofilm, the biofilm including biofilm matrices, the support generating at least one support spectral band and the biofilm matrices generating at least one biofilm spectral band when illuminated by light;

(b) subjecting the support and the biofilm matrices to the cleaning process to be assessed and evaluated; and

(c) evaluating the cleaning process by evaluating the support for remaining biofilm matrices by spectroscopic analysis including:

(i) contacting the support with a biofilm-specific indicator;

(ii) illuminating the support with light;

(~~ii~~ iii) receiving light reflected from the support;

(iii iv) generating an electrical signal indicative of the support and the biofilm-specific indicator remaining biofilm matrices;

(iv v) separating components of the electrical signal attributable to the at least one support spectral band and the at least one biofilm-specific indicator spectral band; and

(v vi) analyzing the components of said electrical signal attributable to each of said spectral bands to generate an output display representative of residual biofilm matrices remaining on said support after said cleaning process.

12. (Original) The method of claim 11, wherein the light is in the infrared range.
13. (Original) The method of claim 11, wherein the light is in the ultraviolet range.
14. (Previously Presented) A cleaning efficacy system comprising:
 - a simulated endoscope comprising a length of tubing having at least one lumen, a biofilm coating including biofilm matrices, a biofilm-specific indicator, and at least one filter, wherein the biofilm coating, biofilm-specific indicator and filter are in fluid communication with the tubing;
 - a light source selected to detect the biofilm-specific indicator; and
 - a light detector selected to detect light from the light source;wherein the biofilm-specific indicator specifically binds to the biofilm matrices of the biofilm coating.
15. (Previously Presented) A simulated endoscope device comprising:
 - a length of tubing, the tubing having at least one lumen;
 - a biofilm coating including biofilm matrices; and
 - a biofilm-specific indicator, the biofilm coating and the biofilm-specific indicator being in fluid communication with the tubing;wherein the biofilm-specific indicator specifically binds to the biofilm matrices of the biofilm coating.

16. (Original) The simulated endoscope device of claim 15, further comprising at least one filter for preventing portions of the biofilm coating from exiting the tubing; wherein the at least one filter is in fluid communication with the tubing.
17. (Original) The device of claim 15, wherein the tubing is transparent and flexible.
18. (Original) The device of claim 15, wherein the tubing is adapted for connection to an endoscope cleaning device.
19. (Original) The device of claim 15, further comprising a first connector attached to one end of the tubing, the first connector adapted to couple the simulated endoscope device to an endoscope cleaning device.
20. (Original) The cleaning efficacy system of claim 19, further comprising a second connector, the second connector adapted to couple the simulated endoscope device to an exit port of an endoscope.
21. (Previously Presented) The device of claim 15, wherein the simulated endoscope device is disposable.
22. (Original) The device of claim 15, wherein the biofilm-specific indicator is provided in a frangible chamber.
23. (Original) The device of claim 22, wherein the frangible chamber is inside the tubing.
24. (Original) The device of claim 15, wherein the biofilm coating is present on an inner surface of the tubing.
25. (Original) The device of claim 15, wherein the biofilm coating is present on a support contained within the tubing.

26. (Previously Presented) An endoscope cleaning assembly comprising:
- a) an endoscope cleaning device comprising at least one cleaning chamber, at least one fluid reservoir, a fluid transfer system, and a control system; wherein the control system selectively transfers fluid from the fluid reservoir, through the fluid transfer system, to the cleaning chamber, and selectively transfers water from a water source, through the fluid transfer system, to the cleaning chamber;
 - b) a simulated endoscope device comprising hollow tubing, a biofilm coating including biofilm matrices, a biofilm-specific indicator that specifically binds to the biofilm matrices of the biofilm coating, and at least one filter; wherein the biofilm coating, biofilm-specific indicator, and filter are in fluid communication with the hollow tubing; and
 - c) at least one connector for fluidly connecting the simulated endoscope device to the endoscope cleaning device.
27. (Previously Presented) A method of cleaning an endoscope comprising:
- (a) attaching the endoscope to an endoscope cleaning device;
 - (b) attaching a simulated endoscope device to the endoscope cleaning device, the simulated endoscope device comprising hollow tubing having at least one lumen, a biofilm coating including biofilm matrices, a biofilm-specific indicator that specifically binds to the biofilm matrices of the biofilm coating, and at least one filter, wherein the biofilm coating, the biofilm-specific indicator, and the at least one filter are in fluid communication with the tubing;
 - (c) running a cleaning and disinfecting cycle of the endoscope cleaning device;
 - (d) analyzing the simulated endoscope device to determine the effectiveness of the cleaning cycle by determining the presence or absence of biofilm matrices after the cleaning cycle, wherein the presence of biofilm matrices

indicates the cleaning cycle was ineffective; the absence of biofilm matrices indicates the cleaning cycle was effective; and

- (e) repeating steps (a) through (d) until the amount of biofilm matrices detected falls below a predetermined level, indicating the endoscope is clean and disinfected.

28. (Currently Amended) A method for assessing and evaluating a cleaning process for cleaning an instrument comprising:

providing a simulated instrument contaminated with biofilm matrices, the biofilm matrices being provided on a support positioned within the simulated instrument;

subjecting the simulated contaminated instrument to the cleaning process to be assessed and evaluated; and

evaluating the cleaning process by analyzing the simulated instrument for the presence of remaining biofilm matrices, including:

introducing a biofilm indicator to the support, and detecting any indicator present on the support, wherein the biofilm indicator binds to extracellular portions of the biofilm matrices.

29. (Cancelled)

30. (Previously Presented) The method of claim 28, wherein the simulated contaminated instrument includes a length of tubing.

31. (Previously Presented) The method of claim 1, wherein the step analyzing the support for the presence of remaining biofilm matrices comprises introducing a biofilm indicator to the support, and detecting any indicator present on the support, wherein the biofilm indicator binds to extracellular portions of the biofilm matrices.

32. (Previously Presented) The method of claim 1, wherein the step analyzing the support for the presence of remaining biofilm matrices comprises breaking a frangible

vial positioned inside an interior of the support to expose any remaining biofilm matrices to a biofilm indicator contained within the frangible vial.

33. (New) A method for assessing and evaluating a cleaning process comprising:
- providing biofilm matrices on a support;
 - subjecting the support and biofilm matrices to the cleaning process to be assessed and evaluated; and
 - evaluating the cleaning process by analyzing the support for the presence of remaining biofilm matrices, including:
 - introducing a biofilm indicator to the support, and detecting any indicator present on the support, wherein the biofilm indicator binds to extracellular portions of the biofilm matrices.